Pa."; (metal box attached to the *Niagara Thermo-Cyclopad*) "Thermo-Cyclopad Model 10."

ACCOMPANYING LABELING: Copies of a brochure designated "General Directions For Use" and leaflets designated "Miracle of Science . . . At Last . . . Two of mankind's greatest healers" and "Miracle Science . . . Niagara Cyclo-Massage."

RESULTS OF INVESTIGATION: The *Niagara Thermo-Cyclopad* consisted of a rectangular pad with an electrical attachment at one end. The pad was approximately 23½ inches long, 15½ inches wide, and 1¾ inches deep. The electrical attachment had a control box connected to it by means of electrical wiring, and the control box had a connection for plugging into household current. In operation, the pad could be heated by means of electric current, and it also could be made to vibrate by means of its built-in electrical mechanism.

The *Niagara Hand Unit* consisted of a rounded metallic object approximately 10 inches long and 3½ inches in diameter at the largest part. It had an electrical wire connector and control box which, when plugged into the household current, caused the unit to vibrate. The slender end of the *Niagara Hand Unit* had a rubber cup attachment.

LIBELED: 11–15–56, Dist. Minn.

CHARGE: 502 (a)—the labeling accompanying the devices, when shipped, contained false and misleading representations that the devices provided an adequate and effective treatment for impaired circulation, arthritis, bursitis, rheumatism, lumbago, numbness of the extremities, fibrositis, nervous tension, muscle spasm, impaired muscle and joint mobility, insomnia, and renewing one's life; and 502 (f) (1)—while held for sale, the labeling of the devices failed to bear adequate directions for use in preventing and overcoming calcium deposits; in overcoming "locked joints" and sinus congestion; in enabling diabetics to stop taking insulin; in overcoming prostate trouble, asthma, hay fever, respiratory conditions, and baldness, which were the conditions for which the devices were intended and for which they were recommended orally by Ralph E. Dixon in promoting the sale of the devices.

DISPOSITION: 1–2–57. Default—delivered to the Food and Drug Administration.

5326. Schlessing Ultrasoniseur devices. (F. D. C. No. 33565. S. No. 18–735 L.)

QUANTITY: 75 devices at Los Angeles and Santa Monica, Calif.

SHIPPED: Between 7–1–51 and 9–4–52, from St. Louis, Mo., by A. Schlessing & Co., Inc.

ACCOMPANYING LABELING: Pamphlets entitled "Therapeutics by Ultrasonics"; leaflets entitled "Please Read Carefully. The Schlessing Ultrasoniseur . . ." and "that they may WALK again . . ."; sheets entitled "Reports on Ultrasonic Physical Medicine from American Users"; form letters headed "Dear Doctor:"; and guarantees and order blanks regarding Schlessing Ultrasoniseur.

LIBELED: 9–5–52, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the devices, when shipped and while held for sale, differed from, and their quality fell below, that which they purported and were represented to possess since their ability to produce total sound output (ultrasonic) differed materially from the ability which they were represented to possess and the output meter (dosimeter) did not accurately gauge the energy density output of the devices; 502 (a)—the labeling of

the devices, when taken as a whole as well as through specific claims, and in the setting in which it was presented, contained false and misleading representations that the devices would provide an adequate and effective treatment for the cure of "abscesses, arthritis, arthrosis deformans, asthma bronchiale, morbus bechterew, bronchiektasy, claudicato intermittens, furunculosis, sciatica, carbunculosis, lumbago, mastitis, myalgia, panaritia, paronychosis, periarthritis humeroscapularis, phlegmones, prostata hypertrophy, sinusitis maxillaris, ulcus cruris, effusions of the joints, abscesses of perspiratory glands, gingivitis, stomatitis, paradentosis, pulpitis, infiltrations, especially granulomes, bursitis, Dupuytren's contracture, endangitis obliterans, fistulae, lymphangitis, paronychia, polyarthritis rheumatica, postoperative pains, morbus raynaud, tendovaginitides, trigeminal neuralgiae, thrombophlebitides, ulcus ventriculi, kidney stones, spinal arthritis, gum boils, kidney colic, gastric ulcer, and asthma"; 502 (a), the following statements contained in the labeling of the devices were misleading: in leaflets entitled "Please Read Carefully," "This Machine Is Absolutely Safe," "that they may WALK again . . .," "Is the Schlessing Ultrasoniseur Difficult to Operate? Not at all. The technique if [sic] the very simplest. No special skill, no involved instructions and no long experience is necessary to use the Schlessing Ultrasoniseur properly. Is the Schlessing Ultrasoniseur Safe? Yes. With ordinary precautions. Ultrasoniseur treatments are absolutely painless. There are no contra-indications. No danger of deep burns, tissue damage or irritation. Equally important, there are no possible harmful effects to the person administering treatment."; and 502 (f) (1)—the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended.

DISPOSITION: 10–22–52. Consent—claimed by A. Schlessing, St. Louis, Mo. The above-described accompanying labeling was delivered to the Food and Drug Administration, and the devices were released under bond to the claimant to be brought into compliance with the law.

Following the entry of the decree, the claimant arranged to ship back to St. Louis, Mo., 47 devices that actually were seized under the libel. Thereafter, 6 of the devices were reconditioned from a physical standpoint to the satisfaction of the Department of Health, Education, and Welfare; and reconditioning of the other 41 devices was suspended until a final decision was made regarding the legality of claimant's proposed method of distribution of the 6 reconditioned devices to licensed California chiropractors, in whose possession the devices were seized at the outset of the libel action. The Department refused to release the devices for such distribution; and on 5–24–54, the claimant filed with the United States District Court for the Southern District of California a motion to compel administrative approval of claimant's proposed method of distributing the devices.

On 2–10–55, after a hearing in the matter, the district court issued its findings of fact and conclusions of law and an order denying the claimant's motion. On 5–17–55, the district court filed a final order directing the claimant to return the devices to the United States marshal and directing the marshal to offer the devices for sale under conditions to be approved by the Department of Health, Education, and Welfare. The claimant appealed to the United States Court of Appeals for the 9th Circuit; and, on 9–24–56, the following opinion was handed down by that court:

FEE, *Circuit Judge:* "This is a review of the denial of a motion by Schlessing to compel administrative approval of a method of distributing certain devices

designated as 'The Schlessing Ultrasoniseur' in the manner proposed by him. All these devices had been condemned in an action for the seizure of seventy-five of these devices prosecuted in the United States District Court for the Southern District of California. The six Ultrasoniseurs here in question were among those sequestered in that action.

"Schlessing, as claimant, on October 22, 1952, agreed to a Consent Decree of Condemnation. By its terms all of these devices then in possession of the court, to the number of forty-seven, were adjudged adulterated and misbranded as alleged in the libel and were condemned under 21 U. S. C. A. § 384 (a). These articles, upon condemnation, were subject to destruction. However, in accordance with the stipulation for consent to the entry of such decree, it was therein provided that claimant was allowed the privilege of distributing such articles when released in the discretion of the administrative body. One provision in the consent decree declares in substance that the claimant shall not distribute the devices until he shall have obtained a written release from the head of the agency. Specifically, it was agreed and the Consent Decree of Condemnation provided that:

> Claimant shall make no distribution of said articles or any part of them except in strict accord with such term and conditions as may be included in said written release.

The decree also contains other provisions:

> Ultrasonic therapy cannot be employed safely and efficaciously by the layman in self-medication, but requires competent supervision in its administration. Adequate directions for unsupervised lay use cannot be written for ultrasonic devices, within the meaning of 21 U. S. C. 352 (f) (1). Interstate distribution which would not violate the Federal Food, Drug, and Cosmetic Act must therefore comply with the regulations which exempt devices from bearing adequate directions for use in their labeling. (21 C. F. R. § 1.106, as amended.) One provision of these regulations exempts a device which is shipped to "a practitioner licensed by law to * * * use or direct the use of the device." (21 C. F. R. § 1.106 (e))

Also:

> The Claimant shall not sell or dispose of said articles or any part thereof in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act, or the laws of any State * * * in which they are sold or disposed of.

"The Consent Decree of Condemnation further expressly retains in the court the jurisdiction to issue further orders, which permitted the court to order destruction of all of these devices on the same terms as could have been originally done.

"The District Court heard the motion and received a stipulation as to the issue to be tried, as follows:

> Is a Chiropractor, who is licensed under the California Chiropractic Act, a practitioner licensed by law to use or direct the use of devices such as the six reconditioned ultrasonic therapeutic devices involved in this case, so as to satisfy the requirements of 21 C. F. R. § 1.106 (e), as amended, and exempt the devices from complying with 21 U. S. C. 352 (f) (1)?

Upon this basis, the District Court issued findings and conclusions and a decree requiring claimant to return the devices at his own expense to be offered for sale 'in such manner and under such conditions as shall be approved by the Los Angeles District of the Food and Drug Administration, Department of Health, Education, and Welfare.'

"The decree must be affirmed. Upon condemnation, the District Court had power and authority to have these devices sold or destroyed under conditions such as are here laid down. The claimant may have entered into a contract which he now regrets, but the terms of the consent decree are clear and unambiguous. He made the release of the devices by the agency the sole criterion. He agreed that the court could issue further orders. He cannot now claim that, if he had known the terms of release would be what they now turn out to be, he would never have made the bargain.

"The practice of medicine and chiropractic in California is regulated by the legislature and administrative boards of the state. There is no law, regulation or decision of that state which forbids the shipment of an Ultrasoniseur into its boundaries. It is a mooted question whether a chiropractor can use such a device, but it is one for the courts and agencies of California to regulate. The agency has no jurisdiction or authority to attempt to regulate the practice of medicine or chiropractic in that state.

"The trial court was led into passing on a matter of state law and administrative discretion of the legislature and the agencies of California. Therefore, the final judgment and decree is affirmed, but the court is constrained to eliminate from the findings and conclusions all references to the nature of chiropractic, ultrasonic therapy and the practice of medicine and of chiropractors in California and all other matters which are here disapproved. The findings relating to the consent decree and the agreement not to ship the machines without release by the administrative agencies and the agreement that the court should make further orders carrying out the original condemnation and sale are left standing.

"Remanded, affirming the final decree herein. The modifications of the findings and conclusions need not be physically made. The appeal is dismissed."

Following the above opinion, the case was remanded to the district court; and, on 11–27–56, pursuant to the order of the district court, the United States marshal destroyed the 47 devices which had been seized.

PRESENCE OF A HABIT-FORMING NARCOTIC WITHOUT WARNING STATEMENT

5327. Amobarbital sodium and phenobarbital sodium. (F. D. C. No. 39189. S. Nos. 17–585 M, 21–661 M, 21–678 M.)

INDICTMENT RETURNED: 2–18–57, E. Dist. Pa., against Milton A. Calesnick, t/a Addison Laboratories, Philadelphia, Pa.

ALLEGED VIOLATION: On 4–14–55, the defendant caused to be given to a firm engaged in the business of shipping drugs in interstate commerce an invoice containing a guaranty that the ampuls of *phenobarbital sodium* and *amobarbital sodium* covered by the invoice were not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 4–14–55, the defendant caused to be delivered to the holder of the guaranty, at Philadelphia, Pa., under the above invoice, ampuls of *phenobarbital sodium* which were adulterated and ampuls of *amobarbital sodium* which were adulterated and misbranded.

In addition, the defendant caused to be shipped, on 4–22–55, from Pennsylvania to Virginia a number of ampuls of *amobarbital sodium* which were adulterated and misbranded.

LABEL IN PART: (Ampuls) "Amobarbital Sodium 7½ gr. [or "3¾ gr."] Sterile–Intravenous" and "5 cc. Ampoule Sodium Phenobarbital Contains: 2 Grains–Dry Powder–Sterile–Intramuscular."